

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. Status of the claims**

Pending are claims 1, 2, 4, 5, 7-14, 16-21 and 24-29. Claim 6 is newly cancelled. Claims 3, 15, 22 and 23 were previously cancelled. Claim 1 is amended, without prejudice or disclaimer of subject matter removed by amendment. No new matter is added.

Claims 2, 8-14, 16-21, and 24-29 are withdrawn. Applicant respectfully requests entry and consideration of the withdrawn subject matter upon the identification of allowable subject matter in the generic or linking claims.

Claims 1, 4, 5 and 7 are under examination, and are rejected.

**II. Rejection under 35 U.S.C. § 103**

Pages 3-7 of the Action maintains the rejection of claims 1, 4, 5 and 7 as allegedly obvious over the combination of WO 00/07023 to Aoyagi, as found in U.S. Patent No. 7,316,915 (Aoyagi III), in combination with Aoyagi II (WO 99/06836, equivalent to EP 0 967 484 (EP '484) and U.S. Application No. 09/269,897). Applicant respectfully traverses the rejection.

*First*, the cited art does not teach or suggest the *surprising advantageous effects* of the present invention, as shown in Example 4, Tables 1 and 2. There, treating a sample containing HCV with a combination of (1) an acidifying agent and (2) a cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule, an HCV antigen in the sample is effectively released and, simultaneously, antibodies binding to the HCV antigen are effectively inactivated. Such a remarkable advantage cannot be expected from the disclosures in the cited references.

**Second**, the present invention succeeds despite teaching away in the prior art. The Office acknowledges that Aoyagi III does not teach or suggest the use of an acidifying agent (Action at page 4, first full paragraph), but alleges that this defect is remedied by US Application No. 09/269,897 (Aoyagi II). It is alleged that page 25 of Aoyagi II teaches acidifying, an assertion that overlooks the plain language of page 25, which states:

***The acid treatment of serum can cause false-positive results since the treatment irreversibly denatures some of serum proteins*** resulting in the formation of precipitates that in most cases hinder pipetting after the treatment of samples, and precipitates that engulfed the denatured proteins are adsorbed to the solid phase at the time of measurement and thereby may be detected as a density. In addition, ***another problem arises because when the antigen of interest is nonspecifically engulfed in the precipitate, the amount of antigen that reacts with the probe decreases resulting in a decrease in sensitivity.***

The inventors of the present invention have found that the acid treatment combined with ***the guanidine treatment can resolve the problems associated with the acid treatment*** such as precipitate formation and the conflicting problems associated with the guanidine treatment, and thereby have completed the present invention.

(emphasis added). Thus, Aoyagi II starts by identifying the serious *problems associated with acidification*: both false positives *and* false negatives. These problems are only overcome by the use of *guanidine*. Accordingly, a combination of Aoyagi II and Aoyagi III *requires* the presence of guanidine, and *teaches away* from a treatment that uses acid *without* guanidine.

Despite the clear teaching in Aoyagi II that acid *must* be paired with guanidine, the presently claimed method uses (1) an acidifying agent and (2) a cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule. Guanidine is not required. Thus, the success of the present invention, and its surprising advantageous effects outlined above, runs contrary to the teaching of the art.

For the foregoing reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection.

**CONCLUSION**

Applicant believe that the present application is now in condition for allowance.  
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date December 6, 2010

By Simon J. Elliott

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 295-4726  
Facsimile: (202) 672-5399

Simon J. Elliott  
Attorney for Applicants  
Registration No. 54,083